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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/750,357 | 12/29/2000 | Katsuhiko Tomita | Q62299 | 6888 |

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EXAMINER

BROWN, JENNINE M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1755 | 9 |

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------|-------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/750,357 | TOMITA, KATSUHIKO |
| | Examiner | Art Unit |
| | Jennine M. Brown | 1755 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-4 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) 1-4 is/are rejected.

7) Claim(s) ____ is/are objected to.

8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. ____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.

4) Interview Summary (PTO-413) Paper No(s) ____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: ____.

DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities: "a molecular recognition layer formed on a sensor face of a chemical CCD, said molecules recognition layer selectively capture molecular of certain chemical substances." should read "a molecular recognition layer formed on a sensor face of a chemical CCD, said molecular recognition layer selectively capture molecules of certain chemical substances."

Appropriate correction is required.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Sawada, et al. (US 6255678 B1).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Sawada, et al. teach a chemical CCD having a plurality of potential wells, arranged two dimensionally, in which electric charges are injected into the potential wells and the chemical quantity is converted into an electric charge corresponding to the sizes of the potential wells; a molecular recognition layer formed on a sensor face of a chemical CCD, selectively captures molecules of a certain chemical substance (col. 2, l. 9-13; col. 4, l. 7-17, 34-65; col. 5, l. 7-40; col. 6, l. 47-53; col. 8, l. 22-41; col. 8, l. 66 - col. 9, l. 48).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hafeman, et al. (US 5164319) in view of Marks, et al. (US 6203758).

Hafeman, et al. teach a chemical based CCD detector which uses AC, DC or pH as the sensing means as well as p and n doped electrodes in individual wells for using a molecular recognition layer for biochemical detection where charge is proportional to the quantity of a detected chemical (Figure 1; col. 2, l. 26-51; col. 3, l. 9-29, 40-58, 63-66; col. 4, l. 10-68; col. 5, l. 1-17; col. 6, l. 26 – col. 7, l. 8; col. 7, l. 38-68; col. 9, l. 51-59; col. 10, l. 6-34, 47-58; col. 10, l. 62 – col. 11, l. 32; col. 15, l. 25-32, 53-61; col. 16, l. 45-48; col. 18, l. 66 – col. 20, l. 16).

Hafeman, et al. do not specifically teach the molecular recognition layer over the sensor which uses molecular imprinting techniques for DNA in the polymer. Marks, et al. teach a molecular recognition layer over the sensor using molecular imprinting techniques for DNA where the imprinted polymer is used instead of a lipid bilayer or monolayer which was previously disclosed by Hafeman, et al. (col. 2, l. 39-44; col. 3, l. 38-40; col. 4, l. 43-65; col. 8, l. 25-50; col. 19, l. 11-25; col. 22, l. 49-54; col. 25, l. 30-32, 35; col. 26, l. 1-64).

It would have been obvious to one of ordinary skill in the art to modify the apparatus of Hafeman, et al. to use the molecularly imprinted polymer of Marks, et al. because the templated polymer material would be specific to the templated DNA therefore a more accurate response to an unknown sample could be measured. This would decrease the amount of sample necessary to be used for the apparatus and increase the efficiency of the response of the apparatus as well.

Response to Arguments

Applicant's arguments filed in Response (paper #8) have been fully considered but they are not persuasive.

According to Sawada, et al., which is considered prior art to the instant application and commonly owned by Applicants, Figure 6 shows a cell (24) for accommodating a sample (23) where substrate (22) bounds cell at bottom and an electrode (25) brings the potential of the sample to a specified high level with respect to the substrate and applying a voltage across substrate causes the sensing section (6) to be in the depleted condition (causes "wells" and "barriers"). Figure 7 is an enlargement of Figure 6 where the sensor sections (13) on the substrate (22) are used to convert the pH to electric charges which go to the output section (14) for converting the transferred electric charges into output signals. The electric charge section (8) comprises horizontal CCD (8H) and vertical CCD (8V).

Similarly, the mechanism employed by Hafeman, et al. is that there is a measurement of surface potential between at the interface of the insulative layer and the medium which is related to the presence and amount of analyte in the assay medium (col. 3, l. 40-58). The region of applied DC potential employed for the measurement is neither forward nor reverse biased because it is found that the rate of change in the DC applied potential is largest, when the circuit is operated at or near the flat band potential of the semiconductor provided the surface potential at the first (semiconductor electrode) and the second (counter electrode) change differently as a result of change in the composition or concentration of analyte (col. 9, l. 26-33) thus

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reacting as a chemical CCD. The assay medium can be a polymerized gel, lipid bilayer, polystyrenes, polyacrylamides, polyacrylates, polyolefins (col. 6, l. 62 – col. 7, l. 8) complexes of binding pair members with unbound species are also contemplated using antibody antigen, enzymes, conjugate binding pairs, sugars, haptens, receptors, ligand receptor pairs (col. 10, l. 47 – col. 11, l. 22). Marks was combined to specifically teach DNA added to the polymer and that the polymer may be molecularly imprinted which was not specifically suggested by Hafeman, et al. but would be one of the available techniques since they are known in the art and are used on similarly made substrates.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

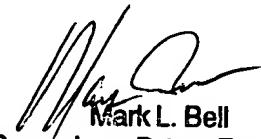
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennine M. Brown whose telephone number is (703) 305-0435. The examiner can normally be reached on M-F 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Bell can be reached on (703) 308-3823. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 879-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

jmb
July 21, 2003



Mark L. Bell
Supervisory Patent Examiner
Technology Center 1700